

## REMARKS

### **I. Introduction**

Having now received the final Office Action mailed on August 11, 2006, Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the reasons that follow.

### **II. Status of the Claims and Summary of Amendments Thereto**

Claim 1 is amended to delete "hydrogen" from the definition of  $R^2$ . Dependent claim 2 is revised accordingly. The PTO previously withdrew from examination claims 4-7, 11-13, and 15-27. After entry of the foregoing amendments, therefore, claims 1-27 will be pending.

The amendments to the claims do not add new matter. Because the amendments reduce or eliminate the outstanding issues, and thereby place the claims into better condition for allowance or appeal, Applicants respectfully urge the PTO to enter the amendments.

### **III. The Office Action**

Applicants gratefully acknowledge the PTO's withdrawal of its rejection of claims based on Mathis *et al.* At issue presently are the PTO's concerns over obviousness-type double patenting and grounds for rejection tied to newly cited Klunk *et al.* The amendments to the claims and commentary below should obviate each ground for rejection.

#### **A. Provisional Obviousness Type Double Patenting**

The PTO maintained its provisional rejection of claims 1-3, 8-10, and 14 as being allegedly obvious over claim 24 of co-pending application No. 10/388,173 ("the '173 application") for the reasons stated before. Office Action at page 2. In support of its rejection, the PTO alleged that the claims of each application "are directed to compounds that have radiolabeled atoms." Office Action dated January 26, 2006 at page 4. In particular, the PTO conceded that the '173 application has claims that, for the recited compounds, do not specify the locations of the radiolabels. In contrast, the present claims do embody such specificity.

Nonetheless, the PTO contends that claim 24 of the '173 application renders the present claims obvious. Applicants respectfully traverse this ground for rejection.

Applicants could frame no better rebuttal of the rejection than what the PTO has set forth already. Where, as here, the application at issue is the later-filed application, a one-way determination of obviousness is needed in resolving the issue of double patenting; that is, whether the invention defined in a claim in the application would have been anticipated by or is an obvious variation of subject matter of a claim in the cited application. *See* MPEP § 804(II)(B)(1)(a), *citing In re Berg*, 140 F.3d 1438, 46 USPQ2d 1226 (Fed. Cir. 1998).

Thus, it is incumbent upon the PTO to establish that the generic provision for a radiolabel in the compounds of claim 24 of the '173 patent somehow anticipates or renders obvious the present claims that do, in fact, require certain radiolabels at specified positions. By the PTO's own commentary on point, however, it is apparent that nothing in claim 24 of the '173 application suggests the selection of the particular radiolabels recited in the present claims. Claim 24 likewise does not point toward the radiolabel substitution patterns evidenced here.

Absent a suggestion or motivation to implement these structural features, the subject matter of the present claims cannot be deemed an obvious variant of the compounds recited in claim 24. By the same token, grant of the present claims would not constitute an improper, time-wise extension of Applicants' exclusive rights in a patent maturing from the '173 application. Accordingly, Applicants urge the PTO to reconsider and withdraw this rejection.

#### **B. Rejection of Claims Under 35 U.S.C. § 102(b)**

The PTO rejected claims 1-3 and 14 for alleged anticipation Klunk *et al.*, *Life Sciences* 69: 1471-84 (2001). Office Action at page 4. In particular, the PTO relied upon the disclosure by Klunk of the species designated in the reference as [N-methyl-<sup>11</sup>C]6-Me-BTA-1. Applicants traverse the rejection to the extent that the stated grounds are deemed relevant to the present claims.

The cited species disclosed by Klunk requires the presence of hydrogen at the position corresponding to substituent  $R^2$  in the present claims. Yet,  $R^2$  in the present claims does not provide for hydrogen. Klunk cannot be anticipatory, therefore, and Applicants courteously urge the PTO to withdraw this rejection.

**C. Rejection of Claims Under 35 U.S.C. § 103(a)**

The PTO rejected claims 1-3 and 14 for alleged obviousness over Klunk. Office Action at page 5. The PTO advanced four scenarios that purportedly establish Klunk's compound [N-methyl- $^{11}\text{C}$ ]6-Me-BTA-1 as homologous in structure and function to a number of compound variants within the present claims. Scenarios (1) and (2), per the PTO's designation, presume a homologous relationship between compounds where  $R^2$  is H or methyl ( $-\text{CH}_3$ ), while scenarios (3) and (4) require  $R^2$  to be H.

Since Klunk supports none of these scenarios, as they might apply to the present claims, Applicants respectfully traverse the rejection.

No structural nexus exists between Klunk and claims 1-3 and 14 because [N-methyl- $^{11}\text{C}$ ]6-Me-BTA-1 requires, per Klunk, that the substituent corresponding to  $R^2$  must be H, whereas the present claims require  $R^2$  to be a non-radioactive or radioactive halo. Klunk manifests no *a priori* principle or guidance by which one of ordinary skill would have made a halo-substituted derivative of [N-methyl- $^{11}\text{C}$ ]6-Me-BTA-1. Absent a suggestion of this type, the claims cannot be said to encompass a series of homologous structures, inclusive of [N-methyl- $^{11}\text{C}$ ]6-Me-BTA-1.

Klunk thus does not substantiate a *prima facie* case of obviousness, and so Applicants respectfully urge the PTO to withdraw this ground for rejection.

**D. Withdrawal of Finality of Office Action and Rejoinder of Method Claims**

The PTO should withdraw the finality of the Office Action because Applicants' previous reply, inclusive of their submission of a declaration pursuant to 37 CFR § 1.132, did not necessitate the new grounds for rejection at issue. According to MPEP § 803.02, the PTO is justified in making an action final where prior art is found during reexamination of a Markush-type claim that has been once rejected over prior art and subsequently amended to avoid that art; this, unless the examiner introduced a new ground of rejection not necessitated by a claim amendment or the submission of an information disclosure statement ("IDS").

In this case, Applicants did not earlier amend the claims, much less revise them to exclude subject matter disclosed by Mathis of record. Nor did Applicants submit an IDS. Instead, as the PTO repeatedly emphasized throughout the Office Action, Applicants merely removed Mathis altogether as a competent reference.

In doing so, Applicants took no action that warrants the PTO in designating the present action as final. Moreover, there is no reason why the PTO could not have also cited Klunk in the previous and non-final Office Action. Thus, the present rejections under Sections 102 and 103 are new grounds for rejection that do not justify finality of this action. It is for this reason that Applicants request the PTO to withdraw the finality.

The foregoing considerations, along with the foregoing amendments and arguments overcoming Klunk, militate strongly in favor of the PTO's expanding its search and examination of the claims. *See* MPEP § 803.02. Specifically, the PTO now should consider withdrawn claims 4-7 and 11-13.

Upon the PTO's determination that claims directed to elected Group I are allowable, Applicants kindly urge the PTO to withdraw the restriction requirement and thereby rejoin withdrawn method claims 15-27 (Group II). Rejoinder should be considered where claims to a nonelected invention depend from or otherwise require all the limitations of an allowable claim. *See* MPEP § 821.04. Because method claims 15-27 ultimately depend from, and therefore require the limitations of, the product claims, the PTO should consider rejoinder of claims 15-27 when the product claims are deemed allowable.

### CONCLUSION

Having now addressed each of the PTO's stated concerns, Applicants respectfully request favorable reconsideration of the application as amended. Examiner Jones is kindly invited to contact the undersigned by telephone if she feels that a telephone interview would be appropriate to resolve any other issues.

Respectfully submitted,

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By S. A. Bent

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5404  
Facsimile: (202) 672-5399

Stephen A. Bent  
Attorney for Applicant  
Registration No. 29,768

**The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.**